

## **REMARKS/ARGUMENTS**

Claims 1, 2-6, 8-15, and 17-25 remain in this application. Claims 1, 3, 4, 6, 17, 19, and 21 have been amended. Support for the amendments to claims 1 can be found throughout the specification and claims, e.g., original claims 4 and 6. Accordingly, no issues of new matter are believed to be raised by the above amendments to the claims.

### **Rejections Under 35 USC 103**

Claims 1-22 were rejected under 35 USC 103(a) as being unpatentable over Ratnaraj et al. (US 5,658,919) in view of Singh et al. (US 5,759,579) and Barry et al. (US 5,055,306). See Pages 2-5 of the Office Action. According to the Office Action:

"Ratnaraj et al. discloses a novel suspension system containing acetaminophen . . . .Singh et al. discloses a pharmaceutical suspension comprising finely divided pharmaceutically active compounds and liquid excipient suspension system comprising water, and the suspending agents xanthan gum and hydroxypropyl methylcellulose . . . .Barry et al. discloses sustained release formulations of pharmaceutically active substances. The formulations comprise a core and coating. . . . It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combine[d] teachings of Ratnaraj et al. (a suspension of acetaminophen) in view of Singh et al. (a suspension of NSAIDs) and of Barry et al. to disclose the claimed invention. One of ordinary skill would use the coating compositions of Barry et al. to coat the drugs of Ratnaraj et al. or Singh et al. for the purpose of providing a sustained release profile for the active agent."

See Pages 3-4 of the Office Action.

As discussed above, Applicants have amended independent claims 1, 17, and 19 to recite that the recited dosage form in the claims comprises (i) particles being substantially covered with one layer of a controlled release composition wherein said controlled release composition is comprised of an insoluble film forming polymer and an enteric polymer and (ii) water. Barry et al does not disclose, or suggest, such particles comprising both an insoluble film forming polymer and an enteric polymer. Rather, the particles of Barry et al. are coated with water insoluble but water swellable acrylic polymer (e.g., Eudragit NE30D ) and a water soluble hydroxylated cellulose derivative (e.g., hydroxypropyl methylcellulose). See abstract of Barry et al. As such, the examples of Barry et al. comprise particles coated

with both Eudragit NE30D and hydroxypropyl methylcellulose. See Examples 1, 3, 5, and 7 of Barry et al. Thus, Barry et al does not disclose, or suggest, such particles comprising both an insoluble film forming polymer and an enteric polymer.

Furthermore, as discussed above, Barry et al. uses a water soluble polymer in its coating for the particles. This polymer would obviously dissolve when the particles were added to a suspension comprising water. Thus, one of ordinary skill in the art would not use the coated particles of Barry et al. in the aqueous suspension systems of Ratnaraj et al or Singh et al.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

## **Conclusion**

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP5021/WEM.

Respectfully submitted,

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